Remarks

Claims 68-74, 76-119, 122-127, 129 and 132-140 were previously pending in the above-identified patent application. In the current communication, new claim 141 has been added. Support for the subject matter of this added claims can be found at for example, page 17, lines 24-27, and Figure 5c. No new matter has been added. Upon entry of the current amendment, claims 68-74, 76-119, 122-127, 129 and 132-141 will be pending and in front of the Office for further consideration.

Applicants respectfully request reconsideration in view of the amendment above and the remarks below. This communication includes Applicants' response to the comments in the Office action dated July 1, 2011, where the rejection under 35 USC 103 was maintained with claims 68-74, 76-91, 93-97, 99-109, 111-119, 122-127, 129 and 132-140 assertedly being unpatentable over Weiner et al.(U.S. Patent No. 5,466,233; herein "Weiner") in view of Rosenman et al. (U.S. Patent No. 6,478,776; herein " Rosenman"). Applicants continue to traverse the rejection.

The Office claims that in the Applicants' specification there is no disclosure or support that the distinction between linear or non-linear is through following the longitudinal axis of the device. Applicants disagree. There is clear support in Applicants' specification distinguishing a body member shape that is non-linear versus one that is linear, as defined by following the longitudinal axis of the device. See for example Figures 1-5c, and page 8, lines 1-7. The "non-linear shaped body member" can include, for example, a "coil shape" and a "zig-zag shape." A device that extends "along its length" (see page 12, line 19), including devices of the current application as well as those in Weiner, inherently have a longitudinal axis. However, one clear difference between the current application and Weiner is that Weiner does not describe an ocular implant that has a non-linear shaped body member following the longitudinal axis of its device.

The Office argues the conical or rounded outer surface shape of Weiner constitutes a non-linear shaped body member according to the Applicants' claims. Again, Applicants' disagree. It is noted that the Applicants' specification describes shapes of the outer surface of the body member (e.g., a circular cross-section, or alternatively have square, rectangular, octagonal or other cross-sectional shapes; see page 12, lines 16-19) as well as at the distal end (e.g., the distal

end 6 may be pointed or beveled; see page 21, lines 10-12), but these are not stated to constitute a "non-linear body member."

It has also been pointed out that the Applicants' specification distinguishes over linear shaped body members as described by Weiner in Applicants' background section on page 3, lines 15-20:

> *U.S. Pat. No. 5,466,233 describes a certain tack for intraocular drug delivery. This device has an end that is positioned in the vitreous cavity while the head remains external to the eye and abuts the scleral surface. The tack contains a fixation portion to attempt to retain attachment within the eye. Because the overall shape of the capsule is linear, the amount of drug that may held by the device and the surface area through which the drug may be delivered is limited. (underlining our emphasis)*

Applicants maintain that a non-linear shaped body member is not taught or suggested by Weiner.

Weiner's insertion process is described in detail in column 15, lines 20-45. Weiner's tack is essentially inserted straight through the scleral tissue so the post passes right into the vitreous. The "slight twirling motion" which the Office refers to does not suggest a non-linear device, because even if "slight twirling motion" were performed, it would only cause movement of Weiner's cone or plug-shaped implant around its linear longitudinal axis (col. 5, line 35). The non-linear configuration of the Applicants' claimed device, on the other hand, results in the body member passing through the scleral tissue at an angle. A "slight twirling motion" does not provide a reason for modification of the Weiner device towards what the Applicants are claiming.

The advantageous substantially straight insertion method of Weiner (for example, using Weiner's arrangement of Figure 15), could not be achieved by modifying the Weiner's device to a non-linear shape. Replacing Weiner's cone or post with a coil-shaped device, such as Rosenman's, as the Office is suggesting, would cause scleral tissue damage. A coil being pushed straight through the scleral tissue, without the proper form of insertion that is described only in the Applicants' specification, would result in tissue damage.

Applicants maintain that Weiner makes no suggestion to modify its device to provide a cross sectional diameter of the body member of 0.5 mm or less (a radius of 0.25 mm), or a diameter in the range of 0.25 mm to 0.5 mm, according to Applicants claims 139 and 140,

respectively. The Office argues that reducing (Weiner's) cross-sectional diameter (towards Applicants' claimed range) would not considerably limit the amount of drug that could be placed in the device of Weiner. Applicants disagree. Weiner, for example, in column 5, lines 38-40, state that the maximum width f (corresponding to the cross section of the device) is from about 1 mm to 3 mm. Even for the lowest value in the Weiner range which is 1 mm diameter for this preferred range (a radius of 0.5 mm), this would mean that per unit length, the loading capacity of Weiner's device would be reduced by 75%. $(1 - (0.25mm^2/0.5mm^2))$. This would be a very significant reduction in loading capacity, and Weiner cannot be construed to suggest this. To reduce the cross-sectional diameter would considerably limit the amount of drug that could be placed in Weiner's device, and this would be contrary to the teaching of Weiner, which is to provide sustained drug delivery device that is capable of staying positioned in the vitreous region (see column 1, lines 19-26; column 2, lines 40-50; and column 6, lines 33-41).

Applicants continue to emphasize that there is nothing in Rosenman that teaches using its myocardial implants for delivery of drugs to the eye. There is no term "eye", "ocular," "ophthalmic", or any term specifically describing eye anatomy in Rosenman. One of skill in the art of ocular drug delivery would not have looked towards devices designed for use in cardiac tissue as taught by Rosenman for at least the reason that the eye is an anatomically unique area of the body, which presents particular considerations for the delivery and treatment with a bioactive agent. Rosenman is primarily focused on myocardial implants and the treatment of heart diseases using these myocardial implants. One of skill in the area of ocular drug delivery would not have looked towards Rosenman at the time of the invention.

Applicants continue to argue that a problem solved according to the current invention is substantially increasing the drug load for intraocular drug delivery, while not obscuring the central visual field, while concurrently minimizing disruption to ocular tissue during the implantation process. On the other hand, as conveyed in column 3, lines 35-67, Rosenman addresses particular problems in the area of cardiac drug delivery for the treatment of heart disease. Rosenman states that prior art polymeric microsphere formulations used for the treatment of heart disease were problematic because they do not provide optimal release kinetics, they can escape into the arterial blood system, and they can also increase the risk of embolic events. Therefore, the problem solved according to Rosenman is providing an implant that contains the drug substance during its delivery to the myocardium and residence there so that

problems of drug not being at the correct location for cardiac treatment in the body are avoided. Importantly, the Rosenman myocardial implant is not required to have a non-linear or coiled shape. The Office acknowledges this. The cardiac implants shown in Figures 24, 25, and 26 of Rosenman have a linear configuration (dart-like), and do not have a non-linear or coiled shape. Yet these linear dart-shaped implants of Rosenman still solve the problems of cardiac drug delivery. Therefore, the non-linear coil-like configuration is not critical to solving the cardiac drug delivery problem discussed in Rosenman. In reference to *In re Oetiker*, 977 F.2d 1443 24 USPQ2d 1443 (Fed. Cir. 1992), if the prior art reference is not in the Applicants' field of endeavor, it must be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. This is not the case for Rosenman

The problem that Rosenman solves with its technology is not reasonably pertinent to the particular problem with which the Applicants were concerned. Without the guidance of the Applicant's own specification, there would have been no reason to identify the coil shaped design of Rosenman's myocardial implant and use it instead of the plug-shaped body member.

Applicants submit that the claims are patentable over the cited references and respectfully request that the rejections under 35 USC 103 to be withdrawn.

Conclusion

It is respectfully submitted that this communication is fully responsive to the current Office Action, and that the claims in their current form are patentable over the cited art and should be passed to issue. The Examiner is invited to telephone the undersigned in the event that such communication is deemed to expedite prosecution of this application.

Respectfully Submitted,

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